UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA and THE STATE OF ILLINOIS, *ex rel.* SAMUEL ENLOE, *et al.*,	)	
Plaintiffs,	)	Case No. 20-cv-1169
v.	)	Hon. Steven C. Seeger
HERITAGE OPERATIONS GROUP, LLC *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Samuel Enloe has returned with a second amended complaint in this *qui tam* action against Heritage Operations Group, LLC and Green Tree Pharmacy. Heritage operates long-term care facilities (meaning nursing homes) in Illinois. It gets its prescription medication from Green Tree.

Enloe, as the relator, claims that Heritage and Green Tree dispensed medication to residents of Heritage's facilities without a valid prescription, in violation of the Controlled Substances Act. And then, they requested and received payment for that medication from Medicare, despite the lack of a valid prescription. Enloe alleges that the scheme violated the False Claims Act.

This Court granted Defendants' motion to dismiss the first amended complaint, and granted leave to amend. *See* 8/18/22 Mem. Opin. and Order (Dckt. No. 50). Enloe filed a second amended complaint. He dropped his claim under the Illinois False Claims Act, and

added new claims under the Controlled Substances Act, as well as a claim of unjust enrichment. Once again, Defendants responded with a motion to dismiss.

For the following reasons, the Court grants Defendants' motion to dismiss the second amended complaint.

Background

At the motion-to-dismiss stage, the Court must accept as true the complaint's well-pleaded allegations. *See Lett v. City of Chicago*, 946 F.3d 398, 399 (7th Cir. 2020). The Court "offer[s] no opinion on the ultimate merits because further development of the record may cast the facts in a light different from the complaint." *Savory v. Cannon*, 947 F.3d 409, 412 (7th Cir. 2020).

The Court assumes a general familiarity with the gist of the case, given this Court's prior ruling on the last motion to dismiss. *See* 8/18/22 Mem. Opin. & Order, at 13 (Dckt. No. 50). Even so, Enloe has now filed a second amended complaint, and each pleading must stand on its own two feet. "It is axiomatic that an amended complaint supersedes an original complaint and renders the original complaint void." *Flannery v. Recording Indus. Ass'n of Am.*, 354 F.3d 632, 638 n.1 (7th Cir. 2004).

The case is about the prescription drug practices by Heritage (a nursing home company) and Green Tree (a pharmacy). More specifically, the case is about how they dispense controlled substances to nursing home residents after hours, when a pharmacist is not available.

Enloe basically alleges that Defendants are dispensing Schedule II drugs (pain medication) without a valid prescription in violation of the requirements in the Controlled Substances Act. *See* Second Am. Cplt., at ¶ 1 (Dckt. No. 55). And then, Defendants are submitting claims for payment to Medicare. *Id.* at ¶ 2.

Relator Samuel Enloe owns and operates Critical Care Rx Pharmacy. *Id.* at ¶ 12. Critical Care Rx Pharmacy serves long-term care residents. *Id.* Enloe previously worked for Omnicare, Inc., another pharmacy serving nursing homes. *Id.* As it turns out, Omnicare got sued by the DEA for improperly dispensing controlled substances without a prescription. *Id.* at ¶ 105. So the claims must have a familiar ring.

Heritage operates 40 or more long-term care facilities (*i.e.*, nursing homes) in Illinois, catering to elderly and infirm individuals. *Id.* at ¶¶ 1, 13–14. Green Tree is a long-term care pharmacy, dispensing drugs to residents of nursing homes and other long-term care facilities as a Medicare-approved Part D sponsor. *Id.* at ¶¶ 3, 15. The same family owns Heritage and Green Tree, so the companies have a close business relationship. *Id.* at ¶ 15.

Green Tree provides prescription medication to the residents of Heritage's long-term care facilities. *Id.* at ¶ 68. Typically, a pharmacy needs a written prescription signed by a physician to dispense Schedule II controlled substances (like opioids) to a patient. *Id.* at ¶ 24.

But pharmacists at Green Tree aren't available 24 hours a day, 7 days a week, 365 days a year. The pharmacists work normal business hours, give or take. They're gone after 5:30 p.m. on weekdays. *Id.* at ¶ 6. They are unavailable after 2:00 p.m. on Saturdays, and they are out all day on Sundays. *Id.*

That unavailability poses an issue for the nursing home facilities managed by Heritage. The company manages dozens of facilities with thousands of patients, and they are an "elderly and infirm clientele." *Id.* at ¶¶ 1, 3, 13. Sometimes they need care after normal business hours. That is, sometimes the residents need pain medication when no pharmacists are available.

Heritage and Green Tree manage that situation by using so-called Emergency Narcotic Kits. Basically, the care facilities have emergency kits that contain Schedule II drugs. If a

resident needs pain medication, the nurse contacts a physician, and the physician gives an oral order to obtain the drug from the Emergency Narcotic Kit and give it to the patient. *Id.* at ¶ 6. "As Green Tree is closed after a certain time, the nurse's quickest means of obtaining the ordered narcotic is from the Emergency Narcotic Kit." *Id.*

Then, the doctor leaves a voicemail with the pharmacy. *Id.* at ¶ 70. Green Tree has a Pharmacy Narcotic Box Policy that allows physicians to call in prescriptions after hours. "The physician can call in a prescription into Green Tree at (309) 432-3451 ext. 1038. If after 5:30 p.m., the physician can leave a message on the x1038." *Id.* at ¶ 94.

At times, Enloe suggests that Heritage might be dispensing drugs from the Emergency Narcotic Kit without *any* prescription at all, even an oral one left on the Green Tree voicemail. *Id.* at ¶ 71. "Should the pharmacy conclude a valid prescription does not exist, the pharmacy obtains a prescription from the practitioner to attempt to cover the drugs that were administered the night before without a valid prescription." *Id.*

Each day, Green Tree (the pharmacy) exchanges each Emergency Narcotic Kit for a new one, and thus replenishes the supply. *Id.* at ¶ 72. The pharmacy reconciles the contents of an opened Emergency Narcotic Kit, and thus accounts for any missing controlled substances. *Id.* If "the pharmacy conclude[s] a valid prescription does not exist [for the missing narcotics], the pharmacy obtains a prescription from the practitioner to attempt to cover the drugs that were administered the night before." *Id.*

Heritage also provides a prescription to the pharmacy, which might be backdated. Someone from Green Tree "contacts the nurse to enquire about a valid prescription. If a valid prescription is not available, the nurse is asked to obtain a backdated prescription from the practitioner to account for the previous night's activities." *Id.*

So, pharmacists are cut out of the loop before the patients receive the drugs, because pharmacists aren't available after hours. Defendants are "bypassing the pharmacist's required role altogether." *Id.* at ¶ 5. And as Enloe sees it, cutting pharmacists out of the loop violates the "letter and spirit" of the Controlled Substances Act. *Id.* at ¶ 7.

Enloe, a pharmacy owner, believes that pharmacists must have a seat at the table. *Id.* at ¶ 12. In his view, "Heritage and Green Tree's actions violated both the spirit and the letter of the CSA by enabling nursing home staff to order Schedule II drugs and immediately obtain them from the Emergency Narcotic Kit without confirmation that a pharmacist had exercised his/her professional judgment about whether these controlled substances were issued for a legitimate medical purpose and appropriate in form, strength and quantity for the resident based on a valid prescription from the prescriber." *Id.* at ¶ 7.

Enloe believes that the whole thing is a scheme to defraud because pharmacists aren't giving the green light before doctors administer the drugs. "Defendants utilized a scheme to defraud as follows: Defendants' practice from approximately the beginning of 2014 through at least the date the complaint was filed was that when a nursing home resident needs pain medication during off hours and there is no current order for a Schedule II pain reliever, the nurse on duty calls the available practitioner for an order. Then, because there are no hard stops in place preventing the nurse from doing so, the nurse goes to the unlocked, unsecured and unrestricted supply of Schedule II drugs, whereupon the nurse may take what he or she needs to address the patient's needs. Because Green Tree does not operate 24 hours a day, the on-call doctor is not required to, and cannot, forward a prescription to the Green Tree pharmacist to review and authorize the nurse to administer the Schedule II drug to the resident." *Id.* at ¶ 70.

The second amended complaint includes a lengthy deep dive into the regulatory framework for dispensing controlled substances. *Id.* at ¶¶ 17–67. Basically, the Controlled Substances Act requires a prescription, but the rules are different depending on whether there is an emergency. In a non-emergency, a doctor must send a written prescription to a pharmacy before dispensing a controlled substance. *Id.* at ¶ 22. But in an emergency, an oral prescription will suffice, and the doctor must follow up with a written prescription within a week. *Id.* at ¶¶ 22–26.

Enloe believes that the use of the Emergency Narcotic Kit violates federal regulations for how a pharmacist must dispense controlled substances. *Id.* at ¶ 26. A regulation covers how pharmacists must dispense Schedule II drugs in emergency situations. *Id.* (citing 21 C.F.R. § 1306.11(d)). That regulation allows a pharmacist to dispense a Schedule II controlled substance "upon receiving oral authorization of a prescribing individual practitioner," if certain conditions are met. *See* 21 C.F.R. § 1306.11(d).

But as Enloe sees it, Heritage is dispensing drugs from the Emergency Narcotic Kit after hours, even when the situation is not an emergency. *See* Second Am. Cplt., at ¶ 74 (Dckt. No. 55); *see also id.* at ¶ 82 (stating that the medical staff can retrieve narcotics from the Emergency Narcotic Kit "only in the situation where a resident encounters an emergency, as defined by 21 C.F.R. § 290.10, and there is not sufficient time to get a prescription filled and delivered by the pharmacy"). "Even though these were not emergency situations, Green Tree dispensed so-called 'emergency' supplies of Schedule II drugs." *Id.*

In other words, Heritage can dispense Schedule II drugs after hours, in one of two ways. Either it is an emergency, or it isn't. *Id.* at ¶ 99. If it is an emergency, then the pharmacy must receive "oral authorization" from the doctor, and must receive a written prescription within one

week. *Id.* If it isn't an emergency, then the doctor must send a written and signed prescription by fax or electronically to the pharmacy "prior to dispensing the drug." *Id.*

But Heritage is not taking steps to ensure that doctors actually leave messages with oral prescriptions. "In furtherance of the scheme, Green Tree provided the staff at long-term care facilities with access to Emergency Narcotic Kits for emergency situations but did not ensure, or even require, that the practitioner had an oral communication with a Green Tree pharmacist prior to dispensing the Schedule II drug." *Id.* at ¶ 84.

Enloe believes that Heritage violates the Controlled Substances Act each time it dispenses a Schedule II drug from the Emergency Narcotic Kit without a prescription. *See id.* at ¶¶ 7–8. And without a prescription, the drugs are not payable by Medicare. *Id.* at ¶ 67 ("A Part D sponsor may only provide benefits for Part D prescription drugs if those drugs are dispensed upon a valid prescription in accordance with law.").

So, by dispensing drugs without a prescription, and then receiving payment from Medicare, Heritage and Green Tree allegedly are submitting false claims to the government in violation of the False Claims Act. *Id.* at ¶ 8.

Basically, Enloe's theory has three parts. Defendants needed a prescription to dispense the drugs. Green Tree (the pharmacy) dispensed the drugs without a valid prescription. And without a valid prescription, Green Tree cannot receive money from Medicare.

In Enloe's view, any after-hours distribution of medication from the Emergency Narcotic Kit when a pharmacist was not available was dispensed without a valid prescription. And any medication submitted for reimbursement through Medicare Part D that was dispensed without a valid prescription involved a false claim to the government. *Id.* at ¶ 8.

The underlying problem is the fact that pharmacists aren't available after hours, and in the meantime, Heritage is dipping into the emergency stash to fill the void. *Id.* at ¶ 76.

At times, Enloe seems to suggest that a care facility can't dispense narcotics to patients – even in emergencies – without the prior approval of a pharmacist. *See, e.g.*, *id.* at ¶ 98 ("Stated simply, Green Tree's and Heritage's formal policy to its management and its staff violated the law each and every time that nurses obtained medication from the Emergency Narcotic Kit *without the authorization of a pharmacist*.") (emphasis added); *id.* at ¶ 5 ("Based on the new procedure, the nurse was granted access to the Emergency Narcotic Kit at any time, regardless of pharmacist authorization or intervention.").

As Enloe tells it, Heritage and Green Tree have followed this practice since 2014. *Id.* at ¶ 76. After doing some back-of-the-envelope estimates, Enloe believes that Heritage has received "hundreds, if not thousands, of requests for Schedule II drugs during off hours." *Id.*; *see also id.* at ¶ 86. And each time Heritage provided the drugs, it violated the Controlled Substances Act. *Id.* "EVERY TIME." *Id.* at ¶ 103 (all caps in original).

Based on personal experience, Enloe is confident that Heritage and Green Tree are violating the Controlled Substances Act. Enloe formerly worked at Omnicare, a company that specializes in serving the needs of nursing home residents. *Id.* at ¶ 12. In 2012, Omnicare settled a case with the DEA about dispensing Schedule II drugs without a prescription. *Id.* at ¶ 105. Green Tree is doing the same thing – it is "dispensing Schedule II drugs during off hours without obtaining a valid prescription dispensed by a pharmacist." *Id.* at ¶ 107.

Enloe sued Heritage and Green Tree under the False Claims Act. The United States declined to intervene. *See* Notice of Election to Decline Intervention (Dckt. No. 16).

This Court dismissed his first amended complaint for failing to sufficiently allege a plausible inference of fraud. *See* 8/18/22 Mem. Opin. and Order (Dckt. No. 50). But this Court gave leave to amend, and Enloe responded with the second amended complaint.

The second amended complaint includes five claims. Counts I and II allege violations of the Controlled Substances Act by Green Tree. *See* Second Am. Cplt., at ¶¶ 113–18 (Dckt. No. 55). Counts III and IV allege the submission of false claims to Medicare by Green Tree in violation of the False Claims Act. *Id.* at ¶¶ 119–127. Count V is about unjust enrichment. *Id.* at ¶¶ 128–131.

The second amended complaint is not entirely clear about whether Enloe is bringing any claims against Heritage, in addition to the claims against Green Tree. The first sentence of paragraph one says that "Mr. Samuel Enloe brings this action against defendant long-term care pharmacy Green Tree Pharmacy." *Id.* at ¶ 1. The second amended complaint does not mention Heritage in any of the counts, either. The last reference to Heritage appears in paragraph 108, and the five counts begin with paragraph 113. All five counts mention Green Tree, but none of the five counts mentions Heritage. *See, e.g.*, *id.* at ¶¶ 114, 117, 120, 125, 129.

That said, the last paragraph of the introduction alleges that "Green Tree and Heritage knowingly caused false claims to be submitted to the Medicare program and made or caused false statements to be made that were material to such claims." *Id.* at ¶ 8. Heritage appears in the caption, too. And paragraph 13 identifies Heritage as a "Defendant." *Id.* at ¶ 13. So, for the sake of inclusiveness, the Court broadly reads the complaint to allege claims against both Defendants.

Defendants responded with a motion to dismiss under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

Legal Standard

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. *See* Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *See AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011).

The Federal Rules raise the bar for claims about fraud. Under Rule 9(b), a plaintiff who is "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." *See* Fed. R. Civ. P. 9(b). The False Claims Act "is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure." *See United States ex rel. Gross v. AIDS Rsch. All.-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005).

"The plaintiff must describe the 'who, what, when, where, and how' of the fraud – 'the first paragraph of any newspaper story.'" *See United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 839 (7th Cir. 2018) (quoting *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009)). That said, "courts and litigants should not take an overly rigid view of the formulation." *See United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 739 (7th Cir. 2021).

Rule 9(b) carves out an exception for allegations about knowledge. Under Rule 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *See* Fed. R. Civ. P. 9(b).

The particularity requirements aim to "discourage a 'sue first, ask questions later' philosophy." *See Heard v. Trax Recs. Inc.*, 2021 WL 3077668, at *3 (N.D. Ill. 2021) (quoting

Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co., 631 F.3d 436, 441 (7th Cir. 2011)). The goal is to protect a defendant's reputation from harm, minimize "strike suits" and "fishing expeditions," and provide notice of the claim to the adverse party. *See Walgreen Co.*, 417 F. Supp. 3d at 1084 (citing *Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016)); *see also United States ex rel. Mamalakis v. Anesthetix Mgmt. LLC*, 20 F.4th 295, 301 (7th Cir. 2021) ("This more rigorous pleading standard guards against the stigmatic injury that potentially results from allegations of fraud.") (cleaned up).

Analysis

The Court will begin with the claims under the False Claims Act. Then, the Court will turn to the claims under the Controlled Substances Act, before ending with the unjust enrichment claim.[1]

I. The False Claims Act (Counts III & IV)

In the False Claims Act, Congress authorized private parties to bring claims on behalf of the federal government against a defendant who defrauds the United States. *See* 31 U.S.C. § 3730(b). The actions are called "*qui tam*" suits, and the party seeking to represent the government's interest is called a "relator." If a relator prevails, he or she is entitled to a big slice of the recovery. *See Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 912 (7th Cir. 2009) ("To encourage private citizens to come forward with knowledge of fraudulent activity, the FCA entitles prevailing relators to collect a substantial share of the funds they recover.").

[1] In their reply, Defendants ask the Court to strike four documents that Enloe attached as exhibits to his response to Defendants' motion to dismiss. *See* Reply in Support of Defs.' Mtn. to Dismiss, at 2 (Dckt. No. 68). Parties cannot amend their complaint in a response brief, but that's not what is happening here. A party can oppose a motion to dismiss by submitting material outside the pleadings "to illustrate the facts the party expects to be able to prove." *See Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). So, the Court denies Defendants' request to strike the exhibits. They're an illustration, not an amendment. And in any event, they do not save the second amended complaint.

The False Claims Act "makes it unlawful knowingly (1) to present or cause to be presented a false or fraudulent claim for payment to the United States, (2) to make or use a false record or statement material to a false or fraudulent claim, or (3) to use a false record or statement to conceal or decrease an obligation to pay money to the United States." *See Prose*, 17 F.4th at 739 (citing *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 822 (7th Cir. 2011)); *see also* 31 U.S.C. § 3729(a)(1)(A), (B), (G).

The first two provisions are at issue here. Enloe alleges that Defendants knowingly (1) presented or caused to be presented a false or fraudulent claim for payment to the United States; and (2) made or used a false record or statement material to a false or fraudulent claim. *See* Second Am. Cplt., at ¶¶ 121, 126 (Dckt. No. 55); *see also* 31 U.S.C. § 3729(a)(1)(A), (B).

A claim under the False Claims Act includes four elements: "(1) falsity, (2) causation, (3) knowledge, and (4) materiality." *See Prose*, 17 F.4th at 740; *see also United States ex rel. Streck v. Takeda Pharms. Am., Inc.*, 2022 WL 595308, at *11 (N.D. Ill. 2022). To survive a motion to dismiss, a relator must allege that (1) defendant made a false claim or statement to receive money from the government, (2) the violation proximately caused the alleged injury, (3) defendant knew that the claim or statement was false, and (4) defendant's misrepresentation was material to the government's payment decision. *See United States ex rel. Lanahan v. County of Cook*, 41 F.4th 854, 862 (7th Cir. 2022); *Mamalakis*, 20 F.4th at 300–01; *Prose*, 17 F.4th at 739–40.

Defendants argue that the second amended complaint fails to adequately allege the submission of a false claim to the government. *See* Defs.' Mem. in Support of Mtn. to Dismiss, at 1, 8 (Dckt. No. 59). The Court agrees.

A claim under the False Claims Act involves fraud, so the complaint must satisfy the heightened pleading standard under Rule 9(b). To bring a claim under section 3729(a)(1)(A) or (B), a relator must allege "specific facts demonstrating what occurred at the individualized transactional level." *See Lanahan*, 41 F.4th at 862. "This includes the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the government." *Id.* (cleaned up).

The second amended complaint falls far short of the heightened pleading standard. The second amended complaint lacks specific facts to carry it over the Rule 9(b) hurdle. The complaint has length, but not heft.

The most striking thing about the second amended complaint is that it hovers at a high level of generality. The pleading describes the general practices of Heritage and Green Tree over an extended period of time. It is long on generalities, and short on specifics.

It's all headline, and no story.

Basically, the second amended complaint says that the procedures at Heritage and Green Tree could allow the facilities to dispense narcotics without following regulatory requirements. A nurse *could* obtain the drugs in an emergency without an oral prescription from the doctor to the pharmacy. The physician *could* neglect to follow up with a written prescription to the pharmacy within a week, too. And for non-emergencies, the physician *could* fail to send a written prescription to the pharmacy before dispensing the drugs.

There are a lot of "could"s and not a lot of "did"s. The complaint does not identify a single instance when a nurse provided a controlled substance to a resident without proper authorization. A general statement about unlawful practices doesn't count for much. *See, e.g.*, Second Am. Cplt., at ¶ 74 (Dckt. No. 55).

For starters, consider the allegation about giving narcotics to residents after hours. The foundation of the case is the premise that Heritage and Green Tree are dispensing controlled substances to residents "without a valid prescription." *Id.* at ¶¶ 1, 2, 5, 8. Even that premise is up in the air.

After reading the complaint, it is not even clear whether it is talking about emergencies, or non-emergencies, or both. The complaint is about "[w]hen a resident at a skilled nursing facility requires pain medication during off hours." *Id.* at ¶ 6. Sometimes a "nursing home resident needs pain medication during off hours." *Id.* The doctor gives the nurse an order, "compelling the nurse to obtain the drug and administer it as soon as possible." *Id.*

That's a rough sketch, at best. There are a lot of unanswered questions.

Is the complaint taking issue with how Heritage and Green Tree handle controlled substances in emergencies, or non-emergencies, or both? And is the complaint taking issue with whether the "emergencies" actually were emergencies?

That is, is the second amended complaint saying that patients are getting controlled substances as if the patients are facing emergencies, when in fact the situations *aren't* emergencies? Is the complaint second-guessing whether the emergencies were emergencies? Or, is Enloe simply alleging that Heritage and Green Tree don't follow emergency protocols when there are emergencies, and don't follow non-emergency protocols when there are non-emergencies?

Again, the regulatory framework varies depending on whether the patient is facing an emergency. If it's not an emergency, then the doctor needs to provide a written prescription to the pharmacy, in advance. But if it *is* an emergency, then an oral prescription will suffice. So, depending on the situation, a "valid prescription" might be written or oral.

More questions come to mind when trying to fill in the gaps. How often does Heritage dispense controlled substances in the middle of the night, and on weekends? And when it does, are those situations emergencies, or non-emergencies? How badly did the patients "need" the "pain medication" in the middle of the night? *Id.*

The second amended complaint doesn't say, one way or the other. The complaint takes it as a given that dispensing drugs after hours requires a "valid prescription." But in the next breath, the complaint acknowledges that a physician can authorize the medical team to dispense narcotics with an *oral* prescription, if there is an emergency need.

By the look of things, maybe the second amended complaint is second-guessing whether the patients were facing emergencies. At times, the second amended complaint appears to assume that Heritage is giving narcotics to residents in the middle of the night even though they have no emergency need. But a complaint cannot satisfy Rule 9(b) through assumptions, without specific facts.

Resting on an assumption seems especially dicey when making a sweeping statement about medical care for specific individuals. Under the regulations, an emergency is a situation when a doctor "determines that immediate administration of a controlled substance is necessary for proper treatment and there are no appropriate alternative treatments available." *Id.* at ¶ 27 (paraphrasing 21 C.F.R. § 290.10).

Second-guessing whether the patients faced emergencies is fraught with peril, especially in the land of Rule 9(b). If a nursing home resident needed pain medicine like oxycodone, fentanyl, or morphine in the middle of the night, presumably there was a sense of urgency. Whether the "need" for pain medication is an emergency might depend on whether you're the one feeling the pain.

More broadly, the second amended complaint seems to take it as a given that a pharmacist must weigh in on whether to give the medicine at all. *See, e.g.*, *id.* at ¶ 5 (referring to the pharmacist's "required role"); *id.* at ¶ 7 (decrying the fact that physicians are administering drugs "without confirmation that a pharmacist had exercised his/her professional judgment about whether these controlled substances were issued for a legitimate medical purpose"). But in other spots, the second amended complaint acknowledges that a doctor doesn't have to pre-clear a prescription with a pharmacist in an emergency. *See, e.g.*, *id.* at ¶¶ 22–26, 83.

The premise of the second amended complaint – that a pharmacist *must* approve it in advance – assumes that there is no emergency. Why? Because a doctor can issue an oral prescription during an emergency. But the complaint is sketchy about whether the patients are suffering emergencies in the middle of the night.

Simply put, the second amended complaint does not squarely allege that any resident ever received a Schedule II controlled substance in the middle of the night when it was *not* an emergency. And at the very least, the pleading doesn't give any specifics.

So, the theory of the second amended complaint seems to have some wiggle. But maybe the second amended complaint isn't second-guessing whether there was an emergency. Maybe the pleading is saying that Defendants don't follow emergency rules during emergencies, and don't follow non-emergency rules in non-emergencies.

Even if that's the theory, the second amended complaint can't get off the ground.[2] The pleading lacks specifics to support the notion that Defendants fail to follow the regulatory framework.

[2] The lack of clarity about the nature of the claim suggests that the second amended complaint could not survive under Rule 12(b)(6), above and beyond the problems about the lack of specific facts under Rule 9(b). The headline is unclear, and the story is untold.

For starters, consider emergencies. The second amended complaint is lackluster when it comes to whether doctors are giving oral prescriptions during emergencies. Again, Enloe alleges that a doctor needs to call in an oral prescription to the pharmacy when there is an emergency need for a controlled substance. *Id.* at ¶ 22. And then, the doctor needs to follow up with a written prescription within one week. *Id.* at ¶ 26.

But the second amended complaint does not squarely allege that physicians at Heritage are failing to give oral prescriptions. And it does not identify a single patient who received a controlled substance without an oral prescription, either.

It is anyone's guess whether any patient at Heritage ever received a Schedule II controlled substance in the middle of the night, during an emergency, without an oral prescription to the pharmacy. But Rule 9(b) requires a lot more than guesswork.

If anything, the second amended complaint seems to speculate when it comes to the non-existence of a prescription. "*Should* the pharmacy conclude a valid prescription does not exist, the pharmacy obtains a prescription from the practitioner to attempt to cover the drugs that were administered the night before without a valid prescription." *Id.* at ¶ 71 (emphasis added).

The same goes for the existence of written prescriptions for emergencies. The second amended complaint does not offer any specific facts to support the general notion that Heritage is failing to send written prescriptions to Green Tree within one week of emergency care.

Specifics are lacking for non-emergencies, too. Again, the second amended complaint acknowledges that Heritage can dispense controlled substances after hours by sending a written and signed prescription to the pharmacy. *Id.* at ¶¶ 24, 99. But once again, the pleading does not offer any example of any patient receiving controlled substances after hours, without a written prescription, when there was no emergency.

The bottom line is that the second amended complaint paints with a broad brush, but never uses a smaller brush to fill in the details. The pleading does not identify a single time when a patient received a controlled substance without Heritage and Green Tree following the proper protocols. The second amended complaint clings to generalities, but Rule 9(b) requires specifics.

The same problem applies to the other part of the claim, to wit, the submission of false claims to the government. Without an underlying violation (meaning dispensing controlled substances without a valid prescription), there is no basis for a false claim. And in any event, the complaint does not identify a single time when any person submitted a false claim to Medicare for payment.

For example, Enloe alleges that "Green Tree submitted requests for payment to Part D Plan Sponsors for Schedule II controlled substances that were dispensed without obtaining a valid prescription." *Id.* at ¶ 120. But he does not (or cannot) allege any details.

The Court has questions. Who submitted these requests for payment? Who were the patients? Who were the nurses? Who were the doctors? When did a single transaction occur? These questions are essential to "the 'who, what, when, where, and how' of the fraud," but they go unanswered. *See United States ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834, 839 (7th Cir. 2018) (quoting *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009)).

To state a claim, Enloe "must state with particularity the circumstances constituting fraud or mistake." *See* Fed. R. Civ. P. 9(b). But Enloe fails to allege "any specific facts demonstrating what occurred at the individualized transactional level." *See Berkowitz*, 896 F.3d at 841.

"In the FCA context, the particularity requirement means that a relator must plead at least some actual examples of false claims." *Singer v. Progressive Care, SC*, 202 F. Supp. 3d 815, 825 (N.D. Ill. 2016). Enloe's general allegations that "Green Tree and Heritage dispensed many, many Schedule II controlled substances without a valid prescription," but that "Enloe does not have sufficient information at this time to determine the total amount of illegally dispensed Schedule II drugs to Heritage residents," do not meet this burden. *See* Second Am. Cplt., at ¶¶ 75–76 (Dckt. No. 55). Even after amending, Enloe's complaint lacks even one specific example of a false claim.

A relator who alleges a lengthy fraudulent scheme "need not plead specifics with respect to every instance of fraud, but he must at least provide relevant examples." *See United States ex rel. John v. Hastert*, 82 F. Supp. 3d 750, 760 (N.D. Ill. 2015); *see also United States ex rel. Sibley v. Univ. of Chi. Med. Ctr.*, 44 F.4th 646, 656 (7th Cir. 2022) ("[T]o defeat dismissal, 'specific representative *examples*' of false submissions are required.") (emphasis added).

Enloe certainly alleges a lengthy scheme. *See* Second Am. Cplt., at ¶ 124 (Dckt. No. 55) ("The scheme began in early 2014 and continues until at least the date the complaint was filed [in 2020]."). But he fails to provide any representative examples of fraudulent claims for reimbursements.

A relator must do more than "simply alleging generally that claims were submitted." *See United States v. Addus HomeCare Corp.*, 2017 WL 467673, at *10 (N.D. Ill. 2017). The relator cannot "merely describe a private scheme in detail," then tack on allegations of fraudulent billing "without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely to be submitted, or should have been submitted to the Government." *See*

United States ex rel. Dolan v. Long Grove Manor, Inc., 2014 WL 3583980, at *3 (N.D. Ill. 2014) (cleaned up).

But that is all Enloe does here.

To put it bluntly, Enloe has not solved the problem that plagued his first amended complaint. The Court stated in its ruling on Enloe's first amended complaint that "[t]o bring a claim under the False Claims Act . . . Enloe would need to allege, with particularity, that Defendants submitted false claims to the government for payment." *See* 8/18/22 Mem. Opin. & Order, at 13 (Dckt. No. 50).

What this Court noted in its prior ruling remains true: Enloe does not allege the time, place, or content of the misrepresentations that allegedly span multiple years and numerous locations. *Id.* at 15. Even after this Court specifically stated it "needs at least some explanation of the timing, location, and scope of Defendants' invalid prescriptions," Enloe failed to provide the who, what, when, where, and how of it all. *Id.* at 20. Enloe's lengthy description of how billing works under Medicare Part D does not suffice.

Instead of fleshing out his allegations with specific details, Enloe devotes valuable real estate to detailed explanations of the regulatory scheme governing controlled substances like pain medication. That's helpful, but that's not enough.

Even if Enloe alleges a violation of a regulatory requirement, a failure to comply with a regulatory requirement is not enough to state a claim for a violation of the False Claims Act. *See Grenadyor*, 772 F.3d at 1107 ("Violating a regulation is not synonymous with filing a false claim."); *see also Berkowitz*, 896 F.3d at 842 (citing *Grenadyor*); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) ("[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."); *United States ex rel.*

Lanahan v. County of Cook, 2020 WL 6894395, at *9 (N.D. Ill. 2020) ("FCA claims do not simply arise from accounting failures, improper procedure, or disregard for regulations.").

And Enloe fails to make a showing that the government's decision to pay would have been different had it known of the alleged regulatory violations. *See United States v. Pfizer Inc.*, 2019 WL 1200753, at *8 (N.D. Ill. 2019); *see also Prose*, 17 F.4th at 740 ("It is not enough simply to say that the government required compliance with a certain condition for payment. The facts must indicate that the government actually attaches weight to that requirement and relies on compliance with it.").

Enloe hasn't sufficiently pled that the government would have made a different decision about reimbursing Green Tree under Part D had it known of Green Tree's practices. Without that showing, Enloe fails to show materiality, another requirement of a False Claims Act claim.

Enloe failed to provide the requested details about the who, what, when, where, and how of the alleged fraud. Enloe lacks sufficient facts to plead a claim under the False Claims Act and Rule 9(b). The Court dismisses Counts III and IV with prejudice.

II. The Controlled Substances Act (Counts I & II)

Enloe also alleges two counts of violating the Controlled Substances Act. Count I alleges a failure to comply with the CSA "by dispensing Schedule II controlled substances without a prescription." *See* Second Am. Cplt., at ¶ 114 (Dckt. No. 55). Count II alleges failure to comply "by causing controlled substances to be administered from Emergency Narcotic Kit boxes provided to long-term care facilities without a prescription, either written or oral." *Id.* at ¶ 117.

The claims fail for a simple reason. There is no private federal cause of action under the Controlled Substances Act. *See, e.g., Illinois ex rel. Strakusek v. Omnicare, Inc.*, 2021 WL 308887, at *10 (N.D. Ill. 2021) ("Like the federal CSA, the ICSA lacks an express private right

of action."); *Illinois Pub. Risk Fund v. Purdue Pharma L.P.*, 2019 WL 3080929, at *2 (N.D. Ill. 2019) ("Notably, the parties agree that there is no private federal cause of action under the Controlled Substances Act."); *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2016), *aff'd sub nom. Safe Streets All. v. Hickenlooper*, 859 F.3d 865 (10th Cir. 2017) (explaining that the Controlled Substances Act does not create a private right of action, nor does it provide a private remedy).

Therefore, Counts I and II are dismissed with prejudice.

III. Unjust Enrichment (Count V)

The last claim is unjust enrichment. Enloe claims "the recovery of all monies by which Green Tree has been unjustly enriched, including profits earned by Green Tree because of dispensing Schedule II controlled substances without valid prescriptions." *See* Second Am. Cplt., at ¶ 129 (Dckt. No. 55). According to Enloe, Green Tree was unjustly enriched when it received the Medicare reimbursement for controlled substances without a valid prescription.

But Enloe has failed to allege that Green Tree submitted false claims for payment by the United States. Therefore, Enloe has failed to allege unjust enrichment. "Under Illinois law, unjust enrichment is not a separate cause of action. Rather, it's a condition brought about by fraud or other unlawful conduct." *See Vanzant v. Hill's Pet Nutrition, Inc.*, 934 F.3d 730, 739–40 (7th Cir. 2019) (cleaned up).

Enloe's substantive claims have failed, so the unjust enrichment claim fails too. *See, e.g.*, *Castaneda v. Amazon.com, Inc.*, 2023 WL 4181275, at *13 (N.D. Ill. 2023); *Lederman v. Hershey Co.*, 2022 WL 3573034, at *7 (N.D. Ill. 2022). There is no unjust enrichment if there is no false claim. In other words, without the identification of any false claim, Enloe fails to allege

any instance when Green Tree was unjustly enriched by accepting Medicare Part D reimbursement.

Count V is dismissed with prejudice.

Conclusion

For the foregoing reasons, the Court grants Defendants' motion to dismiss all claims in the second amended complaint, with prejudice.

Date: February 28, 2024

Steven C. Seeger
United States District Judge